

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 160.000: ACUTE CARE INPATIENT SUBSTANCE ABUSE DETOXIFICATION TREATMENT SERVICES

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160.001: Purpose

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160.003: Citation

105 CMR 160.000 shall be known and may be cited as 105 CMR 160.000: *Acute Care Inpatient Substance Abuse Detoxification Treatment Services*.

160.004: Scope

105 CMR 160.000 replaces and shall be substituted for 105 CMR 160.000 and shall be substituted for 105 CMR 750.700(B) for all residential detoxification programs and shall apply to all entities which provide acute care inpatient substance abuse detoxification treatment services.

All references to residential detoxification programs in 105 CMR 750.000, including sections; 750.010, 750.020, 750.500(D)(2), 750.540(E) and 750.800(C)(1) are hereby deleted. Such entities are subject to licensure or approval under M.G.L. c. 111B, § 6 and c.111E, § 7.

160.020: Definitions

The following definitions shall apply for the purpose of 105 CMR 160.000 unless the context or subject matter clearly requires a different interpretation.

Acute Care Inpatient Substance Abuse Detoxification Treatment Service an inpatient unit that provides short term medical treatment for alcohol and other drug withdrawal, individual medical assessment, evaluation, intervention, substance abuse counseling and post detoxification referrals. The units may be freestanding or hospital based programs.

Administrator The individual duly appointed by the governing body of the agency who is responsible for the day to day operations of the agency operating the service.

Affiliation Agreement shall mean a signed and dated document describing the agreed upon terms of a service relationship between the named parties.

Agency shall mean a legal entity to which a license or approval is granted by the Department for the delivery of the service.

Approval shall mean a certification, in writing, whether full or provisional, issued by the Department to a private or public entity or institution thereof which authorizes it to operate the service.

Building shall mean the physical structure in which the service is provided.

Clinical Supervisor shall mean an individual with a minimum of a doctorate or masters degree in one of the following disciplines or a closely related field: clinical psychology education-counseling, medicine, psychology, nursing, rehabilitative counseling, social work; or a licensed certified social worker; a minimum of one year of clinical supervisory experience and three years of counseling experience.

Clinician I shall mean an individual with a minimum of a masters degree in any of the disciplines mentioned under Clinical Supervisor and who has a minimum of four years of counseling experience, one year of which shall have been related to substance abuse. If providing supervision, one year of supervisory experience is also required.

Clinician II shall mean an individual with a minimum of a masters degree in any of the disciplines

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Commissioner shall mean the Commissioner of Public Health.

Consultation shall mean the presentation of specific patient cases to clinicians of equal or greater expertise for the purpose of feedback, direction and guidance.

Department shall mean the Department of Public Health.

License shall mean certification, in writing, whether full or provisional, issued by the Department to any responsible and suitable agency which authorizes that agency to operate a medical detoxification treatment service.

Licensed Practical Nurse shall mean an individual licensed by Massachusetts Board of Registration in Nursing in accordance with M.G.L. c. 112, § 74A, and knowledgeable in the field of alcoholism and drug addiction.

Licensee shall mean any agency holding a license or approval from the Department to operate the service.

Medical Director shall mean a physician who assumes responsibility for the administration of all medical services performed by the service.

Nurse Practitioner shall mean an individual licensed in accordance with M.G.L. c. 112, § 80B and knowledgeable in the field of alcoholism and drug addiction.

Nurse Supervisor shall mean a registered nurse with a minimum of three years nursing experience, of which one year shall have been related to substance abuse treatment.

Patient shall mean a person applying for admission or admitted to the service.

Physician shall mean an individual licensed by the Massachusetts Board of Registration in Medicine in accordance with M.G.L. c. 112, § 2, and knowledgeable in the field of alcoholism and drug addiction.

Physician Assistant shall mean an individual licensed in accordance with M.G.L. c. 112, § 9G and knowledgeable in the field of alcoholism and drug addiction.

Psychiatrist shall mean a physician licensed by the Massachusetts Board of Registration in Medicine; certified by the American Board of Psychiatry and Neurology or an equivalent body, or eligible for such certification, and knowledgeable in the field of alcoholism and drug addiction.

Psychologist shall mean an individual licensed by the Massachusetts Board of Registration of Psychologists in accordance with M.G.L. c. 112, §§ 118 through 129; and knowledgeable in the field of alcoholism and drug addiction.

Qualified Health Care Professional shall mean a Registered Nurse, Licensed Practical Nurse trained to do physical assessments, Nurse Practitioner or Physician's Assistant duly licensed, certified or registered as such in the Commonwealth of Massachusetts.

Registered Nurse shall mean an individual licensed by the Massachusetts Board of Registration

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Staff shall mean an individual designated by the agency to provide the service on a direct or indirect basis.

Supervision shall mean a regular and specified time set aside to provide training, education and guidance to clinical staff in the management of their clinical cases. Supervision may be provided one-to-one or in small groups of no more than eight individuals.

160.097: Compliance with Requirements

Unless otherwise provided all acute care inpatient substance abuse detoxification treatment services licensed or approved pursuant to 105 CMR 160.000 shall meet the requirements set forth in 105 CMR 160.000.

160.098: Waiver

(A) The Commissioner or his/her designee may waive the applicability of one or more of the requirements imposed on the service by 105 CMR 160.000 upon finding that:

- (1) Compliance would cause undue hardship to the agency;
- (2) The agency is in substantial compliance with the spirit of the requirement; and
- (3) The agency's non-compliance does not jeopardize the health or safety of its patients and does not limit the agency's capacity to provide the service.

(B) The agency shall provide the Commissioner or his/her designee written documentation supporting its request for a waiver.

160.099: Severability

Any section, subsection, paragraph or provision of 105 CMR 160.000 declared illegal or unconstitutional by a court of competent jurisdiction is severable from 105 CMR 160.000

160.100: Requirement of Licensure and Approval

(A) Agencies Requiring Licensure or Approval.

- (1) All agencies shall file an application for licensure or approval with the Department for the establishment or provision of the service.
- (2) Where the service is established and provided by a application for approval for the establishment or provision of the service shall be filed.

(B) Agencies Not Requiring Licensure or Approval. A service established and provided by a department, agency or institution of the federal government does not require licensure or approval under 105 CMR 160.000.

160.101: Application for a License or Certificate of Approval

(A) Applicants for a license or certificate of approval shall submit to the Department an application on an approved form obtained from the Department together with such other documents and materials as the Department shall deem appropriate.

(B) No application shall be accepted unless it is on Department forms, completed in full, and

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(A) The Department has conducted an inspection or other investigation and determined that the applicant complies with 105 CMR 160.000 *et seq.*

(B) The Department has conducted an investigation of the applicant which includes but is not limited to:

- (1) Consideration of past performance as a service provider;
- (2) Financial viability;
- (3) Absence of criminal activity;
- (4) Record of compliance with these or any previous applicable regulations under any past license certificate of approval or contract;
- (5) Possession of all current certificates of inspection issued by the appropriate authorities; and
- (6) Has determined as a result of such investigation that the applicant is suitable to establish or maintain the service.

(C) The Department has determined that there is need for the service at the designated location.

160.103: Change of Name, Ownership or Location

(A) The Department shall be notified immediately, and in writing, of any proposed change in location, name or ownership of the agency.

(B) Transfer of ownership shall be deemed to have occurred when any of the following transfers occurs:

- (1) A transfer of a majority interest in the ownership of an agency;
- (2) In the case of a for profit corporation, transfer of a majority of any class of stock;
- (3) In the case of a non-profit corporation, changes in the corporate membership and/or trustees as the Department determines to constitute a shift in control of the agency;
- (4) In the case of a partnership, transfer of a majority of the partnership interest;
- (5) In the case of a trust, change of the trustee or a majority of trustees;
- (6) A transfer of ownership shall also be deemed to have occurred when foreclosure proceedings have been instituted by a mortgagee in possession.

(C) Within ten days of a change in ownership, the new owner(s) of the agency shall file an application for licensure. This application shall have the effect of a provisional license until such time as the Department acts upon the application.

(D) A license or approval shall not be transferable.

160.104: Collection and Updating of Information

(A) Each agency shall file with the Department such data, statistics, schedules or information as the Department may require for the purposes of licensing and/or monitoring and evaluating a service.

(B) All information submitted under the requirements of 105 CMR 160.000 or otherwise required by the Department shall be kept current by each licensee. Any document which amends, supplements, updates or otherwise alters a required document must be filed with the Department within 30 days of the change.

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160.110: Inspection

- (A) Each applicant or licensee shall be subject to visitation and inspection by the Department:
 - (1) Prior to the granting or renewing of a license or certificate of approval; and
 - (2) for the purpose of monitoring and evaluation.
- (B) If an applicant or current licensee refuses to allow entry and inspection by Department inspectors, the Department may seek an administrative search warrant to authorize entry.
- (C) Refusal by an agency to allow entry to Department inspectors shall constitute adequate and independent grounds for license or approval denial, suspension, revocation and/or refusal to renew.

160.111: Deficiency Statements

- (A) After every inspection in which any violation of 105 CMR 160.000 is observed, the Department shall prepare a deficiency statement citing every violation observed, a copy of which shall be sent to the clinic.
- (B) Every correction order shall be in writing and include a statement of the deficiencies found, the period within which the deficiency must be corrected and the provision(s) of law and regulation relied upon to cite the deficiency(ies). The period shall be reasonable, and, except when the Department finds an emergency dangerous to the health and safety of patients, not less than 30 days from receipt of the correction order.

160.112: Plan of Correction

- (A) The licensee shall submit to the Department a written plan of correction for violations cited in a deficiency statement prepared pursuant to 105 CMR 160.000 within ten business days after the deficiency statement is sent.
- (B) Every plan of correction shall set forth, with respect to each deficiency, the specific corrective step(s) to be taken, a timetable for such steps, and the date by which compliance with 105 CMR 160.000 will be achieved. The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible.
- (C) The Department shall review the plan of correction for compliance with the requirements of 105 CMR 160.113(B) and will notify the licensees of either the acceptance or rejection of the plan. An unacceptable plan must be amended and resubmitted within five business days of the date of notice.

160.120: Renewal of License or Certificate of Approval

- (A) The Department shall send each licensee or holder of a certificate of approval notification of the need to renew its license or approval and the necessary application forms no later than 90 days prior to the expiration of an existing license or approval.
- (B) The licensee or holder shall complete and return the application form within 30 days of its receipt of notification from the Department, together with other information and materials that the Department may deem appropriate.

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160.121: Period of License

The term of the license or certificate of approval shall be for two years from the date of issue, and any renewals thereof shall be for two years, unless otherwise provided.

160.122: Provisional Licenses

(A) All new applicants who have not been previously licensed or approved to provide the service as defined in 105 CMR 000 shall be issued a provisional license or certificate of approval.

(B) When the Department finds that an applicant for licensure or approval has not complied or is unable to comply with all applicable regulations, but has the capability of conforming to all regulations, the Department may issue a provisional license or approval provided that the care given by the agency is adequate to protect the health and safety of the patients.

(C) A provisional license or approval is valid for a period not to exceed six months and may be renewed once for no more than six months. The Department shall issue a provisional license only when an applicant submits a written plan for full compliance. This written plan shall include specific target dates for accomplishing full compliance.

Each licensee shall post in a conspicuous place the current license or certificate of approval issued by the Department.

160.130: Legal Proceedings

Every licensee shall report in writing to the Department any legal proceeding brought against the agency or any person employed by the agency which arises out of circumstances related to the delivery of the service or which may impact on the continued operation of the agency within ten days of initiation of such proceeding.

160.131: Death

The licensee shall orally notify the Department and the patient's known next-of-kin as soon as possible and shall notify such parties in writing within 72 hours of any patient death occurring on site.

160.132: Accident and Fire

(A) The licensee shall notify the Department as soon as possible and in writing within 72 hours of any serious accident requiring medical attention involving patients or staff occurring on the premises and related to the operation of the service.

(B) The licensee shall notify the Department as soon as possible and in writing within 72 hours of any fire or accident resulting in damage to the building.

160.133: Closure

(A) When an agency ceases to operate a service through license or approval denial, denial of a renewal, suspension, revocation, or when the agency voluntarily closes, the licensee shall be responsible for:

(1) In the case of voluntary closure, notifying the Department at least 21 days prior to closure. For the purposes of 105 CMR 160.000 voluntary closure shall include foreclosure

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(B) The Department may, in exceptional circumstances, grant permission for the temporary closure of the service for a period no longer than 30 days when the Department finds that patients will not be affected adversely.

160.140: Grounds for Suspension of License or Approval

The Department may summarily suspend a license or certificate of approval if it decides that the continuation in operation of the service poses an imminent risk to the safety or proper health care of the service's patients.

160.141: Grounds for Denial, Refusal to Renew or Revocation of License or Approval

Each of the following, in and of itself, shall constitute full and adequate grounds on which to deny, revoke or refuse to renew a license or certificate of approval.

(A) Lack of legal capacity to provide the service covered by a license or approval as determined pursuant to 105 CMR 160.102; or

(B) Lack of responsibility and suitability to operate the service, as determined pursuant to 105 CMR 160.102; or

(C) Failure to submit the required license fee; or

(D) Violation of any state statute pertaining to service licensure; or

(E) Failure to give proper patient care to service recipients; or

(F) Violation of any applicable provision of 105 CMR 160.000 and:

(1) Failure to submit an acceptable plan of correction pursuant to 105 CMR 160.112; or

(2) Failure to remedy or correct a cited violation by the date specified in the plan of correction as accepted or modified by the Department; or

(G) Denial of entry to agents of the Department; or

(H) Providing false or misleading statements to the Department.

160.142: Hearings: Procedure

(A) Suspension of a License or Approval.

(1) Upon suspension of a license or approval, the Department shall give the licensee written notice thereof, stating the reason(s) for the suspension. The suspension shall take effect immediately upon issuance of the notice.

(2) If claimed by the agency, an adjudicatory hearing shall be initiated pursuant to 801 CMR 1.00 *et seq.* no later than 21 calendar days after the effective date of the suspension.

(3) In cases of suspension of a license or approval, the hearing officer shall determine whether the Department has proved by a preponderance of the evidence that there existed, immediately prior to or at the time of the suspension, an imminent risk to the safety or proper health care of the service's patients.

160.142: continued

(C) Denial or Refusal to Renew a License or Approval.

(1) Upon receipt of notice that an application for original licensure or approval hereunder has been denied, or an application for licensure or approval renewal has been denied, a proposed licensee may appeal to a hearing officer pursuant to 801 CMR 1.00 *et seq.*

(2) In cases of denial of an original license or approval, or the denial of a renewal of a license or approval, the hearing officer shall determine whether the proposed licensee has proved by preponderance of the evidence that s/he is suitable and responsible for licensure or approval under M.G.L. c. 111B, § 6B or M.G.L. c. 111E, § 7 and 105 CMR 160.102.

(D) Denial, Revocation or Refusal to Renew Based on Lack of Certificate of Inspection. If the Department is notified that the Department of Public Safety or the head of the local fire department or board of health has denied any applicant or licensee a certificate of inspection and that an appeal, if requested, has been duly denied by the Department of Public Safety, the Department shall offer the applicant or licensee an opportunity to submit a current certificate of inspection within two weeks, or within such other time period as the Department shall designate. If the applicant fails to provide a current certificate of inspection within the time period allowed, the Department may deny, revoke or refuse to renew the license or approval of the applicant or licensee.

160.143: Hearings: Scope of Review

(A) Any hearing officer conducting a hearing hereunder shall determine the suitability or responsibility of any licensee or proposed licensee on request of the Department, whether or not the applicant or licensee is licensed at the time the determination is made.

(B) If a hearing officer finds that the licensee or proposed licensee is unsuitable or not responsible under any single provision of 105 CMR 160.102, the hearing officer shall uphold the decision of the Department that the proposed licensee or licensee is not suitable or responsible.

(C) If the hearing officer finds any single ground for denial of, revocation of or refusal to renew a license or approval pursuant to 105 CMR 160.141 the hearing officer shall uphold the decision of the Department to deny, revoke or refuse to renew the license or approval.

160.144: Public Health Council and Judicial Review

(A) The decision of the hearing officer in any adjudicatory proceeding conducted pursuant to 105 CMR 160.142 shall be reviewed by the Department and the Public Health Council. Their decision upon this review shall constitute a final agency decision in an adjudicatory proceeding subject to judicial review pursuant to M.G.L. c. 30A, § 14.

(B) Any licensee or proposed licensee that fails to exercise its right to an adjudicatory proceeding pursuant to 105 CMR 160.142 waives both its right to administrative review by the Department and the Public Health Council and its right to judicial review pursuant to M.G.L. c. 30A, § 14.

160.200: General Requirements

All agencies licensed or approved pursuant to 105 CMR 160.000 shall comply with all state laws and local ordinances applicable to buildings, fire protection, public safety and public health.

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(B) The licensee shall request from the local fire department annual fire inspections in each building. Such inspections shall be recorded and put on file by the licensee.

(C) The licensee shall have a certification of inspection from the local board of health or health department that the facility is in compliance with local and/or state ordinances regarding health, or a statement from the inspecting authority providing conditional approval and indication that the health of the patients would not be endangered in the facility.

160.202: Heating

(A) Each building shall be equipped with a heating system that is sufficient to maintain a minimum temperature of 68°F throughout the building during cold weather. Portable heaters using kerosene, gas or other open-flame methods are prohibited.

(B) The heating system shall be in conformity with the rules and regulations as outlined by the Department of Public Safety under M.G.L. c. 148 as amended.

(C) Plumbing and heating shall be adequate to maintain a comfortable and healthy environment for patients. Hot water supplied to fixtures accessible to patients shall be controlled to provide a maximum temperature of 110°F.

160.203: Lighting

Adequate electric lighting, maintained in good repair, shall be provided throughout the building in accordance with the provisions of the M.G.L. c. 111, § 72C, as amended, and the recommended levels of the Illumination Engineering Society. All electrical installations shall be in accordance with the Department of Public Safety, Board of Fire Prevention Regulations (527 CMR), Massachusetts Electrical Code (527 CMR 12.00), and all local regulations.

160.204: Building Design

(A) The design, construction and furnishings of the building shall be appropriate and flexible enough to accommodate the needs of the patients.

(B) Each site proposed for the delivery of the service shall require the written approval of the Department. Written approval shall also be required for any change in location of an existing service.

160.210: Housekeeping

The licensee shall ensure that the building is maintained in a safe, clean, orderly, attractive and sanitary manner, free from all accumulation of dirt, rubbish and objectionable odor and in good repair.

160.211: Building Maintenance

(A) Floors, walls and ceilings shall be cleaned regularly; walls and ceilings shall be maintained and free from falling plaster.

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(F) All doorways, corridors and stairwells shall be maintained so as to provide free and unobstructed egress from all parts of the building:

- (1) An emergency source of lighting shall be available in all corridors and stairways that lead to the principal means of egress; and
- (2) All stairways shall be equipped with handrails;
- (3) Night lights shall be provided in corridors, toilets and bathrooms.

160.212: Storage Areas

(A) Each building shall have adequate space for storage of equipment and bulk office supplies.

(B) Storage areas, attics and cellars shall be kept safe and free from accumulations of extraneous materials such as refuse, furniture and old newspapers or other paper goods. Combustibles such as cleaning rags and compounds shall be kept in metal cabinets.

160.220: First Aid Supplies

The licensee shall keep first aid supplies in a convenient and safe place ready to be used for minor injuries.

160.221: Basic Life Support

There shall be a minimum of one staff person on each shift who is trained and certified in Cardio-Pulmonary Resuscitation (CPR).

160.222: Emergency Plans

(A) The licensee shall establish a written plan detailing procedures for meeting potential emergencies.

(B) The emergency plan shall include:

- (1) Procedures for the assignment of personnel to specific tasks and responsibilities in emergency situations;
- (2) Instructions relating to the use of alarm systems and signals;
- (3) Procedures for notifying appropriate persons; and
- (4) Specification of evacuation routes and procedures.

(C) The licensee shall post the emergency plans and procedures at suitable locations throughout the building. Staff and patients shall be familiar with the emergency procedures.

(D) The licensee need not conduct emergency drills but shall assure itself that patients are aware of appropriate means for self-preservation and have in place a clear plan for the evacuation of all patients and staff.

160.223: Services for the Handicapped

The licensee shall make reasonable accommodations to serve otherwise qualified persons with disabilities in the most intertraffic setting possible. If elimination of barriers to accessibility is not financially feasible, the licensee shall make all reasonable efforts to refer such patients to an

160.230: General Areas

- (A) Each building shall have sufficient space for reception and office areas.
- (B) Each building shall have sufficient space for the storage of patient records; confidential materials kept at the site shall be under lock and key and so secured that only authorized agency staff shall have access to them.
- (C) Each building shall have sufficient and separate space for group and individual counseling areas
 - (1) These areas shall be furnished and arranged in a manner that is consistent with their use and safeguards the personal dignity and privacy (in terms of both sight and sound) of the patient; and
 - (2) If separate rooms are not provided, the program service areas shall have floor-to-ceiling partitions to assure minimum sound transmission.
- (D) Each building shall have sufficient space for recreation, reading and quiet time.
- (E) The master key to all rooms which may be locked shall be kept where it is available to the shift manager in an emergency.
- (F) The licensee shall provide or make available accommodations for the laundering of residents' clothing.
- (G) Residents' belongings shall be kept in a manner that will protect them from loss, theft, or misuse by others, Except when clinically contraindicated, residents shall have ready access to their belongings.

160.231: Bathrooms

- (A) Bathrooms shall be conveniently located throughout the building.
- (B) Every bathroom door lock shall be designed so that in an emergency the locked door can be opened from the outside.
- (C) Bathrooms shall be designed to ensure privacy with the use of partitions and doors.
- (D) All toilets shall have seats.
- (E) Bathrooms shall either have natural or mechanical ventilation devices.
- (F) Bathrooms shall be in good repair, cleaned frequently and maintained in a sanitary manner.
- (G) Bathrooms shall be supplied with soap, paper towels, toilet tissue and a mirror at all times.
- (H) There shall be separate bathroom and bathing facilities for male and female patients. If separate facilities are not possible there shall be mechanisms in place that will insure private use of the facilities by males or females.
 - (1) Toilets and handwashing facilities shall be provided in a ratio of at least one per ten residents
 - (2) Showers or tubs shall be provided in a ratio of at least one per ten residents

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(B) Sleeping areas shall be designed to promote comfort and provide adequate space and privacy for residents and shall be large enough for the placement of needed furniture and allow for easy passage between beds and other items of furniture.

(1) All rooms shall provide a minimum of 50 square feet per person.

(2) Sleeping areas shall accommodate no more than six persons per sleeping area. Exceptions may be allowed upon written approval of the Department.

(C) No unfinished attic, stairway, hall or room commonly used for other purposes shall be used as sleeping room for any resident.

(D) All sleeping areas shall have direct outside exposure with adequate, unobstructed natural light and adequate ventilation.

(E) Each resident shall be provided with the following basic equipment and supplies:

(1) A comfortable bed with a mattress and bed springs;

(2) An adequate supply of bed linens, blankets, washcloths, and towels in good condition;

(3) A toothbrush, toothpaste and shaving materials when appropriate;

(4) A bedside cabinet, table dresser or adequate drawer space and adequate closet space.

160.240: Food Storage

(A) The licensee shall have a written plan for protecting food from contamination and spoilage during its storage, preparation, distribution and service.

(B) The plan shall address:

(1) Procuring all food from sources that provide assurance that the food is processed under regulated quality and sanitation controls,

(2) Clearly labeling supplies,

(3) Storing all non-food supplies in an area separate from that used for storing food supplies,

(4) Storing perishable foods at proper temperatures,

(5) Ensuring that any walk-in refrigerators or freezers can be opened from the inside even if locked,

(6) Providing adequate hand washing and drying facilities in convenient places,

(7) Thorough cleansing and sanitizing of all working surfaces, utensils and equipment after each period of use, and,

(8) Maintaining frozen foods at temperatures below 10°F.

160.241: Food Handlers

Persons working in the food service area shall be free of infections, communicable diseases and open skin lesions. The licensee's health policies for persons working in the food service area shall be in compliance with state and local health laws and regulations. Patients shall not be responsible for any duties in the food service area as a part of their treatment regime.

160.242: Utensil Storage

(A) The licensee shall provide sanitary storage space in cabinets for the proper storage of dishes, silverware and cooking equipment which shall be maintained in a sanitary manner and in good repair. Dishes shall be washed and rinsed in a manner that is consistent with local health

160.243: Waste Disposal

The licensee shall be responsible for the sanitary disposal of all waste materials in accordance with accepted health practices.

160.244: Meals

- (A) The licensee shall provide a nourishing well-balanced diet to all residents.
- (B) Food preparation areas shall provide adequate work space for the sanitary preparation and serving of all meals.
- (C) The licensee shall provide dining areas which are clean, well lighted, ventilated and attractively furnished.
- (D) The dining room shall be large enough to accommodate all residents but not necessarily simultaneously.
- (E) Any area designated as the dining area shall not be used as a bedroom by any resident or resident staff.

160.300: Organization

- (A) The ownership of the agency shall be fully disclosed to the Department including the names and addresses of all owners or controlling persons whether they be individuals, general and/or limited partnerships, corporate bodies, or subdivisions of other bodies.
- (B) Agencies operating the service shall have a governing body or advisory committee that is representative of the community it serves and that includes in its membership persons knowledgeable about the treatment and prevention of substance abuse.
- (C) The licensee shall keep and maintain an organizational chart and written policy that describes the organizational structure including lines of authority, responsibility, communication and staff assignment.
- (D) The licensee shall appoint a qualified administrator to be responsible for the day-to-day operations of the agency. The administrator shall be on the premises during the workday. In his/her absence a professional staff person shall be designated to act in his/her place.
- (E) Each licensee shall establish a system of business management and staffing to assure that the agency maintains complete and accurate accounts, books, and records, including required financial, personnel, and patient records.

160.301: Goals and Objectives

- (A) Each licensee shall adopt and maintain a current written statement of purpose identifying service goals, objectives, and philosophy. This statement shall be reviewed annually and modified as necessary, reflecting changes in the characteristics of the patients served, changes within the community where the service is located, or recommended changes as a result of an agency evaluation.

160.302: Finances

- (A) The applicant or licensee shall demonstrate financial capability to operate the agency for the licensing period.
- (B) The licensee shall keep and maintain in accordance with state requirements an accurate record of the finances of the agency.
- (C) The licensee shall keep on file an annual budget. Such budget shall categorize revenues by source of funds and expenses by service components.
- (D) The licensee shall establish written procedures and policies for all fiscal operations, including policies and procedures for fee arrangements with patients.
- (E) Each licensee shall have liability insurance.

160.303: Patient Records

- (A) The licensee shall maintain individual patient records.
- (B) The written individual patient record shall include, but not be limited to, the following information:
 - (1) Name, Division Management Information System patient identifiers, date of birth, sex, race/ethnicity, marital status, and primary language if other than English.
 - (2) A complete initial evaluation that includes: social, economic, and family histories, educational and vocational achievements, related legal problems, medical history, drug/alcohol use and treatment history.
 - (3) The referring agency, courts, or person.
 - (4) Sources of financial support.
 - (5) Presenting problem(s).
 - (6) Signed and dated weekly progress notes entered by medical, nursing and counseling staff including the patient's participation in all aspects of the required components.
 - (7) An individual service plan and updates when appropriate.
 - (8) A discharge summary.
 - (9) Aftercare service plan.
 - (10) All necessary authorizations and consents.
- (C) Progress notes shall be current, legible, dated, and signed by the individual making the entry. Group counseling and educational session progress notes may describe the session in general, but the patient's record must also include specific comments on the patient's participation and progress in the group.
- (D) All patient records shall be marked confidential and kept in a secure, locked location.
- (E) Except as otherwise provided in 105 CMR 160.304 or by applicable state or federal law, access to patient records shall be limited to those staff members authorized by the administrator or his/her designee. The licensee shall have a written procedure regulating and controlling access to patient records to staff members whose responsibilities require that they have access.
- (F) The licensee shall not develop any procedure prohibiting Department personnel access to patient records for the purpose of review authorized by law.

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(3) Where a service closes and patients are not referred, the agency shall be responsible for the secure storage of such records. Public notice shall be given regarding the date of service termination and the site at which such records shall be secured. The records shall be sealed and retained for six years from the date of the program's closure. At the end of six years the records shall be destroyed.

160.304: Confidentiality

(A) Patient specific information shall be privileged and confidential and shall only be made available in conformity with all applicable state and federal laws and regulations regarding the confidentiality of patient records, including but not limited to, 42 CFR Part 2, as effective August 10, 1987.

(B) Patient specific information shall only be made available:

- (1) To medical personnel in a medical emergency;
- (2) To qualified personnel for the purpose of conducting scientific research, management audits or program evaluations;
- (3) If authorized by an order of a court of competent jurisdiction, as required by federal regulations; or
- (4) Where authorized by the prior informed consent of the patient.

(C) Patient's informed consent shall be in writing and shall contain:

- (1) The specific name or general designation of the program or person permitted to make the disclosure;
- (2) The name or title of the individual or the name of the organization to which disclosure is to be made;
- (3) The name of the patient;
- (4) The purpose of the disclosure;
- (5) How much and what kind of information is to be disclosed;
- (6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent, or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign in lieu of the patient;
- (7) The date on which the consent is signed;
- (8) A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it; and
- (9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

(D) Any disclosure made, whether it be with or without the patient's consent, shall be limited to information necessary in light of the need and purpose for the disclosure.

(E) Authorization for release of information shall have a duration no longer than that necessary to accomplish the purpose for which it is given.

(F) Unless requested by the patient only the administrator or his/her designee shall release information from patient records.

(G) A request for release of information by a patient shall not be denied.

160.305: Patient Rights

(A) The licensee shall make every effort to safeguard the legal and civil rights of each patient. Each licensee shall adopt and maintain a currently updated set of agency rules which shall state the responsibilities and the rights of patients.

(B) Specific Patient Rights. The licensee shall guarantee patient freedom from physical and psychological abuse. At a minimum, these rights shall include freedom:

- (1) From strip searches,
- (2) To have control over his/her bodily appearance as long as one's appearance does not conflict with the program's policy regarding health, hygiene and treatment plan,
- (3) To examine his/her patient record,
- (4) To challenge information in his/her patient record by inserting a statement of clarification,
- (5) To terminate treatment at any time, unless committed to treatment under M.G.L. c. 123, § 35,
- (6) From signing over his/her public assistance, food stamps, or other income to the licensee except when it is part of a mutual treatment agreement signed by both the patient and the licensee,
- (7) To be informed of his/her patient rights,
- (8) To bathe, shower and meet personal hygiene needs in a reasonable manner at a reasonable time,
- (9) To have regular physical exercise, when clinically appropriate,
- (10) To wear his/her own clothes, unless clinically contraindicated,
- (11) To send and receive sealed letters. Where the licensee deems it necessary, mail shall be inspected for contraband in the presence of the patient.
- (12) To be given regular and private use of a pay telephone, and,
- (13) To have visitors at reasonable times. Visits by the patient's attorney and personal physician shall not be limited.

(C) The agency rules shall also include a written grievance procedure for the resolution of any patient related problem or dispute which arises within the agency.

(D) Prior to any enacting of a rule modifications affecting the areas listed in 105 CMR 160.305(B), the licensee shall submit a written justification to Department prior to implementing such a change.

160.310: Policies

(A) Each licensee shall describe, in writing, the agency's current personnel policies and practices and shall make them available to all staff members.

(B) Such personnel policies shall include a description of:

- (1) The criteria and procedures for hiring, assigning, promoting, and suspending or dismissing a staff member.
- (2) The procedure for handling staff complaints and grievances.
- (3) Provisions for vacations, holidays, paternity and maternity leave, educational leave, sick leave, and other leaves of absence, and fringe benefits.
- (4) Procedures for disciplinary actions.
- (5) Procedures for work performance appraisal.

160.312: Personnel Records

- (A) The licensee shall maintain a personnel record for each employee.
- (B) Such records shall be kept confidential and at a minimum contain:
 - (1) A copy of the employee's application for employment or resume;
 - (2) Evidence that the employee is currently certified, licensed or registered where applicable laws require certification, licensure, or registration;
 - (3) Evidence of training received; and
 - (4) Annual performance evaluations;
 - (5) Evidence of annual Tuberculin skin tests.

160.313: Training

- (A) The licensee shall provide ongoing staff training and supervision appropriate to the size and nature of the agency and staff involved.
- (B) The licensee shall have a written plan for the professional growth and development of all personnel. At a minimum, this plan shall include:
 - (1) Staff training in the requirements of appropriate state and federal laws and regulations;
 - (2) Orientation procedures; and
 - (3) Regular and scheduled in-service training programs.

160.314: Volunteers

Volunteers and student interns may be used only as an adjunct to regular paid staff and not as a substitute for a paid workforce. Student interns and volunteers providing individual and/or group counseling shall be screened, oriented, trained and supervised in a manner consistent with 105 CMR 160.000.

160.320: Staffing Pattern

The agency shall provide adequate and qualified personnel for administrative, medical, clinical and support services necessary to fulfill the service objectives and to satisfy the intent of 105 CMR 160.000.

160.321: Multidisciplinary Team

- (A) In order to meet patient needs a multidisciplinary team shall be employed which includes professionals with a variety of expertise. The team may include physicians, psychiatrists, psychologists, social workers, nurses, substance abuse counselors with Masters or Bachelor degrees in a related field and certified substance abuse counselors.
- (B) The agency shall ensure that patients have access to this expertise on-site or on an on-call basis to the extent required to meet their needs.
- (C) Cases presenting unique issues or of special educational value to staff shall be presented to the multidisciplinary team for consideration. A summary of the multidisciplinary case conference must be included in the patient record.

160.322: Minimum Staffing Requirements

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160.323: Consultation and Supervision

- (A) A Registered Nurse supervisor must be available for adequate supervision and ongoing consultation for all nursing staff.
- (B) Consultation to nursing staff must be available 24 hours per day, seven days per week from a fully qualified physician or psychiatrist, either on site or through an affiliation agreement.
- (C) A Clinician I (with the exception of the individual cited in 105 CMR 160.322(B), shall receive a minimum of one hour of individual or group consultation every two weeks and an additional minimum of one hour per month if he/she is responsible for supervising other staff.
- (D) A Clinician II shall receive a minimum of one hour of individual or group supervision each week.
- (E) A Clinician III shall receive two hours of individual supervision and an additional two hours of individual or group supervision per month.
- (F) Staff who are not full-time employees of the service shall receive supervision in proportion to the number of hours worked, with a minimum of one hour of supervision per month.
- (G) Consultation to staff must be available from a fully qualified physician or psychiatrist, either on-site or through an affiliation agreement. If services are to be available through an affiliation agreement, this agreement shall be reaffirmed yearly.
- (H) Documentation of supervision must be available for review.

160.400: Hours of Operation

The service shall provide care 24 hours a day, seven days per week.

160.401: Admission

- (A) Each licensee shall establish written admission eligibility criteria and shall make such criteria available to prospective patients upon application for admission. A copy of the criteria shall be posted conspicuously in an area frequented by all patients.
- (B) Each licensee shall establish a formal intake procedure for potential new admissions and re-admissions. During the intake session the licensee shall accumulate and record all pertinent patient information to effectively evaluate a patient's eligibility for the service and his/her service needs.
- (C) Patients who do not meet eligibility requirements or who are inappropriate for the agency's service shall, where need exists, be referred to an appropriate service, person, agency or court.
- (D) Each licensee shall maintain a log of applications denied admission.
- (E) Upon admission into treatment, or as soon as the patient is medically cleared, the licensee shall obtain and shall make a part of the patient record:
 - (1) A consent to treatment form,
 - (2) For patients receiving methadone, Form FD-2635, and,

160.402: Orientation

The licensee shall provide a new patient with an orientation which will familiarize him/her with the rules, procedures, activities, policies, and philosophy of the program, including program requirements for participation and disciplinary, termination, and grievance procedures. Written evidence of this orientation shall appear in the clinical record.

160.403: Evaluation and Diagnosis

(A) Immediately upon admission a physical assessment of the patient shall be made by a qualified health professional. Within 24 hours of admission, a complete physical examination shall be completed. If the examination is conducted by a qualified health professional and not a physician, the results of the examination and any recommendations made as a result of the examination, shall be reviewed by the nursing supervisor prior to implementation. For multiple admissions, the time, frequency and interval of a complete physical examination shall be subject to physician discretion.

(B) Upon admission, or as soon as the patients physical condition permits, a thorough personal history shall be obtained.

(C) Both the medical and psychosocial evaluation and medical include an assessment of the patient's psychological, social, health, economic, educational/vocational status; related legal problems; involvement with alcohol and drugs and any other associated conditions. The evaluation must be completed before a comprehensive service plan is developed for the patient.

(D) When the initial evaluations indicate a need for further assessment, the program shall conduct or make referral arrangements for necessary testing, physical examination and/or consultation by qualified professionals.

(E) If the psychosocial evaluation is performed by a Clinician III, it must be reviewed and approved, in writing, by his/her supervisor.

160.404: Service Plan

(A) Each patient shall have a written initial individualized service plan developed based on information gathered during the admission and evaluation sessions. Service plans developed or revised by a Clinician III shall be reviewed and signed by his/her supervisor.

(B) The service plan and any subsequent updates shall include at least the following information:

- (1) A statement of the patient's problem in relation to his/her misuse of alcohol and drugs,
- (2) Service goals with timelines,
- (3) Evidence of patient involvement in formulation of the service plan,
- (4) Aftercare goals,
- (5) The date the plan was developed and/or revised,
- (6) The signatures of staff involved in its formulation or review.

(C) Individual service plans shall be reviewed with the patient and amended, as necessary. A summary of such periodic reviews shall become a part of the patient record.

160.405: Medical Services

(A) Where appropriate, the licensee shall operate in accordance with:

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(B) The Medical Director shall be responsible for administering all medical services performed by the service, be licensed to practice medicine in the Commonwealth of Massachusetts, and where possible have experience in working with substance abusing persons. In addition, the Medical Director, or any other authorized staff physician shall be responsible for the following minimum requirements:

- (1) Ensuring that a medical evaluation, including a medical history has been taken,
- (2) Ensuring that appropriate laboratory studies have been performed, and,
- (3) Signing or countersigning all medical orders.

(C) Physical Examinations. The physical examination shall, at a minimum, include an investigation of the possibility of infectious diseases, pulmonary, liver, and cardiac abnormalities, dermatologic sequelae of addiction and possible concurrent surgical problems. Prior to prescribing, dispensing or administering any drug, the licensee shall assure itself that the drug will not interfere with any other drug(s) the patient has reported taking.

(D) Laboratory Tests

- (1) Each patient shall receive a tuberculin skin test at least every 12 months, when the tuberculin skin test is positive, a chest x-ray,
- (2) When appropriate, the licensee shall also perform the following laboratory tests within 48 hours after admission:
 - (a) Urine screening for drug determination,
 - (b) Complete blood count and differential,
 - (c) Serological test for syphilis,
 - (d) Routine and microscopic urinalysis,
 - (e) Urine for Glucose and Protein (GL/PR),
 - (f) Liver function profile, *e.g.* SGOT, SGPT, *etc.*,
 - (g) An EKG,
 - (h) Australian Antigen HB AG testing (HAA testing), and,
 - (i) A pregnancy test.

(E) Where the drug being dispensed is a narcotic-like substance or a narcotic antagonist, two or more proofs of narcotic or other drug dependence must be present. Such proofs may consist of:

- (1) Two or more positive urine tests for opiate or morphine-like drugs,
- (2) The presence of old and fresh needle marks,
- (3) Early physical signs of withdrawal,
- (4) Documented evidence from the medical and personal history,
- (5) Physical examination, and,
- (6) Laboratory tests.

(F) Pharmacological services shall be provided as needed by staff physicians.

(G) The licensee shall document in the patient record any situation that requires a patient to stay in treatment longer than the prescribed service plan indicated. The record shall be updated every seven days.

160.406: Counseling Services

(A) Services offered shall include:

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- (B) The licensee shall provide each patient who has been medically cleared with a minimum of ten hours of direct service per week, including:
 - (1) At a minimum, one hour of individual counseling,
 - (2) Four hours of group counseling, and
 - (3) Five hours of education, self-help or social rehabilitation.
- (C) Patient assignment to staff should be based on a patient's needs and staff expertise.
- (D) The licensee shall provide case management which shall at a minimum include:
 - (1) Crisis referrals,
 - (2) Health care referrals,
 - (3) Continuum of care referrals,
 - (4) Aftercare referral.
- (E) The licensee shall provide or make referral arrangements for the provision of additional services as needed.
- (F) The licensee shall provide AIDS education to all patients admitted to the service. AIDS education shall be provided by a qualified professional and conform to policies set forth by the Department. Evidence of this AIDS education shall appear in the patient record.
- (G) Where the licensee utilizes an outside agency(ies) for the provision of direct patient services, formal written agreements shall be maintained and reaffirmed every two years.

160.407: Termination

- (A) The licensee shall establish and maintain written procedures detailing the termination process and shall incorporate them into the policies as described in 105 CMR 160.402. These procedures shall include:
 - (1) Written criteria for termination, defining:
 - (a) Successful completion of the program,
 - (b) Voluntary termination prior to program completion,
 - (c) Involuntary termination,
 - (d) Medical discharge, and,
 - (e) Transfers and referral.
 - (2) Rules of required conduct and procedures for both emergency and non-emergency involuntary terminations in accordance with the following requirements:
 - (a) In an emergency situation, where the patient's continuance in the program presents an immediate and substantial threat of physical harm to other patients or program personnel or property or where the continued treatment of a patient presents a serious medical risk to the patient as determined by the medical director or the nurse-in-charge, the licensee may suspend a patient immediately and without provision for further detoxification. The patient shall be afforded an appeal as described in the program policies.
 - (b) In a non-emergency situation, wherein the patient's continuance does not present the immediate and substantial threat or serious medical risk described in 105 CMR 160.407(A)(2)(a), the licensee may not terminate the patient without first affording him/her the following procedural rights:
 - 1. A statement of the reasons for the proposed termination and the particulars of the

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- (C) The discharge summary shall contain, but need not be limited to:
 - (1) Description of the treatment episode,
 - (2) Sobriety status and a description of current drug and alcohol use,
 - (3) Reason for termination,
 - (4) A summary of any disciplinary action taken, including:
 - (a) The reasons therefor, and,
 - (b) Patient notification of appeal, and,
 - (5) Referrals

160.408: Aftercare

- (A) The licensee shall make referral arrangements for the provision of post discharge counseling and other supportive service.
- (B) The licensee shall maintain and make available to patients as needed, a file of available community service which shall include a description of the services, its address and phone number and the name of a contact person.
- (C) Aftercare service referrals shall be documented in the patient record.

REGULATORY AUTHORITY

105 CMR 160.000: M.G.L. c. 111B, § 6; c. 111E, § 7.

Filename: 105160.000 DX.doc
Directory: C:\DPH\Bsas\documents\licensing
Template: D:\Program Files\Microsoft Office\Templates\Normal.dot
Title: 105 CMR 160
Subject:
Author: Glenn Swinson
Keywords:
Comments:
Creation Date: 02/01/02 8:41 PM
Change Number: 2
Last Saved On: 02/01/02 8:41 PM
Last Saved By: Glenn Swinson
Total Editing Time: 1 Minute
Last Printed On: 02/07/02 4:39 PM
As of Last Complete Printing
Number of Pages: 24
Number of Words: 9,732 (approx.)
Number of Characters: 55,476 (approx.)